

(ii) *Calculations.* Calculate the vidarabine content as follows:

$$\text{Percent vidarabine} = \frac{A \times W_s \times f}{(B \times W_u \times 10)}$$

where:

A=Area of the vidarabine sample peak (at a retention time equal to that observed for the standard);

B=Area of the standard peak;

W<sub>s</sub>=Weight of standard in milligrams;

W<sub>u</sub>=Weight of sample in milligrams; and

f=Potency of standard in micrograms per milligram.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(3) of that section.

(3) *Metal particles.* Proceed as directed in § 436.206 of this chapter.

[42 FR 44224, Sept. 2, 1977, as amended at 44 FR 30335, May 25, 1979; 50 FR 19921, May 13, 1985]

## Subpart E—Otic Dosage Forms

### § 455.410 Chloramphenicol otic.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Chloramphenicol otic is a solution of chloramphenicol in a suitable and harmless vehicle. Each milliliter contains 5.0 milligrams of chloramphenicol. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of chloramphenicol that it is represented to contain. It is sterile. Its moisture content is not more than 2 percent. Its pH is not less than 4 and not more than 8. The chloramphenicol used conforms to the standards prescribed by § 455.10(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain the following:

(i) Results of tests and assays on—

(a) The chloramphenicol used in making the batch for potency, pH, specific rotation, melting range, absorptivity, and crystallinity; and

(b) The batch for potency, sterility, moisture, and pH.

(ii) Samples required:

(a) The chloramphenicol used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 20 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the sample diluted with an equal volume of distilled water.

[44 FR 5881, Jan. 30, 1979, as amended at 48 FR 3961, Jan. 28, 1983; 50 FR 19921, May 13, 1985]

## Subpart F—Dermatologic Dosage Forms

### § 455.510 Chloramphenicol dermatologic dosage forms.

#### § 455.510a Chloramphenicol ointment (chloramphenicol cream).

The requirements for certification and the tests and methods of assay for chloramphenicol ointment (chloramphenicol cream) are described in § 455.310c.

#### § 455.510b [Reserved]

#### § 455.510c Chloramphenicol-polymyxin ointment.

The requirements for certification and the tests and methods of assay for chloramphenicol-polymyxin ointment are described in § 455.310d.